K033078

OCT 2 9 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex Ohmeda S/5 Web Viewer and S/5 Pocket Viewer with L-WEB03 Software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

September 27, 2003

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex Ohmeda S/5 Web Viewer and S/5 Pocket Viewer with L-WEB03 Software

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classification appears applicable:

MSX	System, network and communication, physiological monitors	870.2300

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer version (K023497).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use for the modified device is the same as the predicate, Datex-Ohmeda S/5 Web Viewer (K023497). The indications for use for the S/5 Web Viewer is the same as in predicate except that the grammar has been improved. The indications for use for the S/5 Pocket Viewer is the same as in predicate except that the grammar has been improved, and that the term 'generic computer' has been replaced by a term 'generic handheld computer'. There has been no change to the basic technology from the predicate. Changes to the labeling include revised User's Manuals and Brochures.

The Datex-Ohmeda S/5 Web Viewer is a supplementary monitoring application running on a generic PC that is connected to the hospital LAN, either directly or via the Internet. It is based on the World Wide Web and Java technologies, and it is intended to be used for remote viewing of real-time patient information and trends from patient monitors that are connected to the Datex-Ohmeda S/5 Network and Central.
The Pocket Viewer is a Web Viewer version running on a Pocket PC PDA that is connected to the hospital LAN via wireless access within the hospital, or via a mobile connection outside the hospital. The PDA uses a standard WLAN (802.11b) or mobile connections (GSM, GPRS, HSCSD) to gain access to the Hospital LAN and Web Server.
The Web Viewer and Pocket Viewer are not primary alarm sources but decision-making support tools that offer clinicians access to the patient data also outside the patient care area.

The hospital is responsible for ensuring a secure and functional interface between the Datex-Ohmeda S/5 Network and the Hospital LAN, by utilizing, for example, a gateway, router, switch or firewall, as shown in the figure above. If the Web Viewer clients are not connected to a hospital Intranet, a regular hub can be used instead. Wireless LAN access points are required to connect the Pocket Viewer to the WLAN.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The Datex-Ohmeda S/5 Web Viewer is intended to be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.
The Datex-Ohmeda S/5 Pocket Viewer is intended to be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.

Indication for use for S/5 Web Viewer:
The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of an S/5 Web Server and S/5 Web Viewer clients.
The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network.
The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use.
The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source.
The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer:
The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of an S/5 Web Server and S/5 Pocket Viewer clients.
The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network.

The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use.
The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source.
The device is for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer version (K023497) currently in distribution.

Similarities:
The indications for use for the S/5 Web Viewer are the same as in the predicate except that the grammar has been improved. The indications for use for the S/5 Pocket Viewer is the same as in predicate except that the grammar has been improved, and that the term 'generic computer' has been replaced by a term 'generic handheld computer'. The structure and functionality of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer corresponds to the structure and functionality of the Datex-Ohmeda S/5 Web Viewer (predicate). The basic architecture of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer is the same as that of Datex-Ohmeda S/5 Web Viewer (predicate). The revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer can show real-time curves, numeric information, graphical and numerical trends and visual alarms from bedside monitors just like the predicate. The physical network and the PC hardware components used by the revised S/5 Web Viewer and S/5 Pocket Viewer are the same as in the predicate.

Differences:
The following functionality has been added to the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer:
User interface changes:

- The users can configure additional waveform views with fixed parameter sets in addition to the view that is currently displayed on the source monitor.
- Separate parameter configurations for graphical and numerical trends were created, and the maximum number of configurable pages was increased. Division between anesthesia and critical care pages was removed.
- Digit field layouts have been improved.
- Possibility to hide the numeric values of the waveform parameters was added (Pocket Viewer client only) in order to give more space to waveforms.
- In Pocket Viewer - due to small display size - only the highest-level active alarm is indicated in the waveform view with a color-coded symbol, and active alarms can be viewed in a separate Alarm View page. In the Web Viewer the alarms are displayed as in the previous version.
- A separate Demographics page was added to display patient demographic data.
- To make selecting of a patient easier in the small Pocket Viewer display, a possibility to display selected patients first in the patient selection menu was added.
- Viewing of EEG waveforms, and EEG and NMT numeric values and trends were added.
- Possibility to set and change individual user preferences through setup pages that are accessible directly from the client application was added.
- In Pocket Viewer, the patient selection is always made through a Patient menu. The menu is included also in the Web Viewer client, and therefore a possibility to hide the (permanently displayed) monitor selector area has been included in the Web Viewer client.

In addition to the functional changes, the following technical improvements have been implemented in the revised S/5 Web Viewer and S/5 Pocket Viewer:

- The new version supports Microsoft Pocket PC based PDAs in addition to PC based clients.
- SSL (Secure Sockets Layer) encryption is now utilized in securing the communication between the Web Server and the clients.
- The licensing scheme was enhanced from a fixed license of 6 concurrent users to cover license options for 6, 12, 18, 24 or 30 concurrent Web Viewer clients and for 6, 12, 18, 24 or 30 concurrent Pocket Viewer clients.
- Automatic log-off after pre-selected time of inactivity was implemented
- Enhanced event logging for administrative purposes.
- A possibility to define the monitors that individual users can access has been added in the new version.

Summary:
The changes above do not affect safety and effectiveness of the system, and the new Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer, described in this submission, are substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex Ohmeda S/5 Web Viewer and S/5 Pocket Viewer with L-WEB03 Software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 2000 (IEC60950 3rd edition) – Product Safety
- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 (IEC-CISPR 24) – Electromagnetic Immunity
- EN 61000-3-2:1995 + A1/A2/A14, Harmonic Currents
- EN 61000-3-3:1995, Voltage Fluctuation and Flicker
- EMC Directive 89/336/EEC (including amendments)
- Low Voltage Directive 73/23/EEC (amended by 93/68/EEC)
- EN 1441, Medical devices - Risk analysis
- IEC 60601-1-4
- Medical electrical equipment. Part 1: General requirements for safety
- 4. Collateral Standard: Safety requirements for programmable medical systems.
- CAN/CSA-C22.2 No. 60950-00: Safety on Information Technology Equipment.
- UL: IEC 60950 (1999) Third Edition.
- FDA/ODE Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 29, 1998.
- FDA/ODE Guidance for the Off-The-Shelf Software Use in Medical Devices, September 9, 1999.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex Ohmeda S/5 Web Viewer and S/5 Pocket Viewer with L-WEB03 Software as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2003

Datex-Ohmeda
c/o Mr. Joël C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K033078
Trade Name: Datex Ohmeda S/5 Web Viewer and S/5 Pocket Viewer with L-WEB03 Software
Regulation Number: 21 CFR 870.2300
Regulation Name: System, network and communication, physiological monitors
Regulatory Class: Class II (2)
Product Code: MSX
Dated: September 27, 2003
Received: September 29, 2003

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033078

Device Name: Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer with L-WEB03 software

Indication for use for S/5 Web Viewer:

The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Web Viewer clients.

The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network.

The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use.

The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source.

The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer:

The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Pocket Viewer clients.

The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network.

The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use.

The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source.

The device is for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

510(k) Number K033078

(Optional Format 1-2-96)